Attachment B

K100731

510(k) Summary for

Bosworth Air Polisher

Sponsor

Harry J. Bosworth Company
7227 N. Hamlin Avenue
Skokie, Illinois 60076-0399
USA

DEC - 3 2010

Establishment # 1410638

Contact Person: Gary Chuven
Telephone: 1-847-679-3400 ext. 240

Date Prepared: 10 November 2010

Device Name

Proprietary Name:	Bosworth Air Polisher
Common/Usual Name:	Dental handpiece
Classification name:	Dental handpiece and accessories
Regulation:	21 CFR 872.4200
Product code:	EFB

Device Description

The Air Polisher is a hand-held device that contains air and water lines, a capped chamber for the cleaning powder, and a nozzle. This device connects to a standard turbine tube that supplies air and water. When the Air Polisher is connected and activated, a stream comprised of powder, air, and water spray is generated. This spray can be directed on the tooth surface to clean and polish the tooth.

Intended Use

This device is a dental handpiece that is intended for tooth cleaning and polishing by the use of a powder, water, and air spray stream onto the tooth surface.

Technological Characteristics and Substantial Equivalence

The Bosworth Air Polisher and the predicate device AirFlow Master Standard (Electro Medical Systems K073284) are used for cleaning and polishing of teeth.

Both the Bosworth Air Polisher and the predicate device have an identical operating principle. Projection of a powder, water, and air spray stream onto the tooth surface provides the cleaning and polishing action.

Comparison Chart for Determination of Substantial Equivalence

Comparison Item	**Bosworth Prophy Gun - Proposed**	**EMS Air-Flow Master Standard – K073284**
Intended Use	Cleaning & polishing of teeth by the projection of water, air, & dental powder onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.	
Function	Air Polisher	Air Polisher
Cleaning & Preparatory Action	Projection of air/water/powder mixture.	Projection of air/water/powder mixture.
Delivery Control	Dental operatory unit	Dedicated operational unit
Foot pedal Activation	Yes	Same
Water & Air Supply	External	Same
Powder Location	Powder chamber on the handpiece	Powder chamber on the operational unit
Prophy Powder	Bosworth Prophy Powder	Air-Flow Classic
Sterilization Process	Handpiece & powder nozzle: steam	Handpiece & powder nozzle: steam

Performance Testing

The Bosworth Air Polisher was tested to support a minimal reuse life of 130 treatments, which corresponds to 15 hours of use. The Turbine tube connection was tested for integrity to demonstrate that the connection between the Bosworth Air Polisher and the turbine adapter, when subjected to air pressures of 47 – 53 psi, remained intact.

Conclusion Statement

Based on the comparison between the Bosworth Air Polisher and the predicate device AirFlow Master Standard, the clinical information, and on the specific testing performed on the Bosworth Air Polisher, we conclude that the Bosworth Air Polisher is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Gary Chuven
Quality & Regulatory Manager
Harry J. Bosworth Company
7227 North Hamlin Avenue
Skokie, Illinois 60076

Re: K100731
Trade/Device Name: Bosworth Air Polisher
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: November 15, 2010
Received: November 17, 2010

DEC - 3 2010

Dear Mr. Chuven:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A

510(K) Number: K100731

Device Name: **Bosworth Air Polisher**

INDICATIONS FOR USE:

The Bosworth Air Polisher is a dental handpiece used for cleaning and polishing teeth. It projects a spray of water, air, and powder onto the tooth surface. The Bosworth air Polisher is designed to be used by a Dental Professional.It is a prescription device The packaging contains the following statement. "Caution: Federal law restricts this device to sale by or on the order of a Dentist. "

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ X _____ OR Over-the-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100731